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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,657	06/27/2003	Lars G.J. Hammarstrom	R0135B-REG	7065

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EXAMINER

BERCH, MARK L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,657	Applicant(s) HAMMARSTROM ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/27/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to Synthesis of compounds, classified in class 544, subclass 276,277.**
- II. Claims 11-16, drawn to Synthesis of Library, classified in class 435, subclass 4.**
- III. Claims 17-18, drawn to Library of compounds, classified in class 435, subclass 4.**
- IV. Claims 19-22, drawn to reducing a supported pyrimidine, classified in class 544, subclass 311, 312, 216, 322-332 and others.**

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the triamino intermediates can be prepared by alternative methods such as the amination of the 2,4-diamino, 5-halo-pyrimidines.

It should be noted that Group I does not require the Group IV step, as Group I does not require any solid support, and Group IV does not require the step used in Group I since Group I can be used on e.g. just nitro-pyrimidine, which cannot be used to make purines.

The processes of Groups I and II make entirely different sorts of things, since a library is fundamentally different from a single compound.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Brian Buckwalter on 5/10/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claim 11-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 3930005 A.

See the process in columns 5-6 of VII to VIII to X. In the first step, the 6-halo is reacted with benzylamine, to give the 6-benzyl derivative. That corresponds to the starting material in claim 1, in which R3 is benzyl, and the NR2R3 of the reference corresponds to the NR1R2 of claim 1. The reduction of the nitro group which occurs at column 5, line 49 corresponds to the actual step a). The step of VIII to X, corresponds to step b), giving a product which corresponds to R3 of claim 1 as benzyl. Applicants should note that choices in which R5 is alkyl, alkoxy or amino are seen in Table 1, as is a choice in which one or both of R1 and R2 are alkyl. But even without these

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guideposts, it would be obvious to perform the reaction with any variable choices, since the choices for R1, R2 and R3 in the reference are fairly narrow.

Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over US 3930005 as applied to claim 1 above, and further in view of DiLucrezia.

Claim 9 sets for several cyclization agents, including the use of an aldehyde or isothiocyanate plus oxidizing agent. The primary reference uses formamide. Di Lucrezia, page 250, scheme 2, showing the cyclization of 13, depicts the use of both the aldehyde or the isothiocyanate, along with the use of formamide. This clearly conveys to one of ordinary skill in the art that these three are alternatively useable to cyclize the triamino pyrimidine. Hence, it would be obvious to modify the primary reference to use either of the other known methods.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. "Thioalkyl", which occurs in the definition of R5 is not standard nomenclature. Thio as a generic prefix simply indicating the presence of sulfur. It could have a number of possible meanings. It is possible that the term refers to HS-alkyl-, which is properly called the mercaptoalkyl group. It is also possible that it is intended to refer to the alkyl-S- group, which is properly called the alkylthio group. It could possibly refer to the replacement of a carbon in an alkyl with a Sulfur, e.g. CH₃-S-CH₂-. Another alternative is that the sulfur could be a double bonded substituent (rather than a single bonded one as seen in mercaptoalkyl), e.g. CH₃-C(=S)-CH₂-, properly called the thioxo alkyl. There might be some letters missing, so that what was

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intended was thiophenylalkyl, i.e. the alkyl is substituted by thiophene, or possibly thionoalkyl, i.e. alkyl substituted by $=C=S$. This specification gives no clear evidence as to which of these plausible choices was originally intended. A similar problem exists for thioaryl.

2. The nature of the heterocycle formed from NR8R9 is unclear. Other than the N of attachment, what other heteroatoms can be present? What size ring is this, and what is the nature of the bonding in the ring?
3. Claim 5 is not worded correctly. A step cannot comprise a thing. It is suggested that "comprises a" be replaced with "is done in the"
4. Claim 6 is unclear. What level of purity does this require? No more than 1%? $\frac{1}{2}$? 0.1%? There is no way of telling what the standard here is. Likewise claim 7.
5. The term "acyl anhydride" in claim 9 is unclear. Presumably this is an acylated anhydride, but where is it acylated? An anhydride already has two acyl groups attached to an oxygen, and there appears to be no place for a third. What does this look like?
6. In claim 10, a metal complexed with what?

Specification

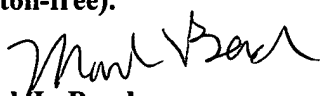
The abstract is objected to. It states that there is a process, but does not state what the process actually consists of. The nature of the compounds is also unknown. The abstract is far too generic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


**Mark L. Berch
Primary Examiner
Art Unit 1624**

5/13/05